

## REMARKS

Claims 1-25 are pending. Claims 1-3, 15-19 and 20 have been amended to address grammatical issues and to correct claim dependencies, and not for reasons related to patentability. Claims 1 and 15-17 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Initially, Applicants note that the claim dependencies for claims 2, 5, 18 and 21 have been changed to address the Examiner's comments on p. 8, lines 3 and 4 of the present Office Action.

### **Rejections Under 35 USC §103**

Claims 1-6 and 17-21 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,432,441 (*Bealin-Kelly et al.*) in view of U.S. Patent No. 4,271,142 (*Puglia et al.*) and U.S. Patent No. 4,260,596 (*Mackles*). Claims 1-25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,060,078 (*Lee*) in view of U.S. Patent No. 4,800,087 (*Mehta*), U.S. Patent No. 4,753,790 (*Silva*), U.S. Patent No. 4,260,596 (*Mackles*), and U.S. Patent No. 6,432,442 (*Buehler et al.*). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Claim 1 as amended is directed to a texture masking dosage form comprising (a) a unitary soft core, which is comprised of a plurality of active agent particles having an average size of greater than about 50µm, a hydrocolloid, and water, and (b) a brittle shell encasing the soft core in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500 µm to about 3000 µm, wherein the

weight ratio of active agent particles to shell is from about 1.0:0.5 to about 1.0:15 in the texture masking oral dosage form.

*Bealin-Kelly et al.* discloses a throat drop that has an edible shell (from 60% to 95%) and an aqueous filling (from 5% to 40%). The filling includes a throat relief agent, water, and a vesicle-forming agent, which encapsulates the throat relief agents. Moreover, the filling may be in the form of a liquid, gel or paste. In *Bealin-Kelly et al.*, it is stated that the vesicles have a number average particle size of from about 1 to about 100  $\mu\text{m}$ .

In contrast, Applicants' invention as recited in claim 1, requires that the active agent particles have an average size of greater than about 50  $\mu\text{m}$ . Thus, the fact that the vesicles used in *Bealin-Kelly et al.* have a number average particle size of from about 1 to about 100  $\mu\text{m}$  does not mean that the active agent particles have an average size greater than about 50  $\mu\text{m}$ . As such, claim 1 is patentable over *Bealin-Kelly et al.*

*Puglia et al.* is cited for disclosing an antacid tablet that has a center portion containing an antacid in the form of a liquid, cream or gel, where gelatin and pectin may be included as possible thickeners in the gel and cream center portion.

*Mackles* is cited for disclosing an edible unit dosage form having an outer shell and a liquid or gel center containing an active agent. The thickness of the shell may vary in the range of about 0.5 to about 3.0 mm.

However, neither *Puglia et al.* nor *Mackles* remedy the deficiencies of *Bealin-Kelly et al.*, since neither teach or suggest active agent particles having an average size greater than about 50  $\mu\text{m}$ .

As such, claim 1 is patentable over *Bealin-Kelly et al.*, *Puglia et al.* and/or *Mackles*, whether considered separately or in any proposed combination.

*Lee* discloses a chewable pharmaceutical dosage form having a core containing an active ingredient and an outer layer.

*Mehta* relates to a chewable taste masked pharmaceutical dosage form. Acetaminophen and ibuprofen are included in the list of suitable actives. In addition, gelatin is identified as an acceptable diluent. However, as Applicants have previously noted, *Mehta* uses a method where a powdered or granular active agent, and diluent or bulking agent are used to form a wet mass utilizing water or a pharmaceutically acceptable solvent. The mixture is subsequently dried, creating a dry pharmaceutical core. See *Mehta*, column 8, lines 29-43. Thus, the pharmaceutical core of *Mehta* is not soft. As such, *Mehta* teaches away from Applicants' claimed invention.

*Silva* teaches a coated comestible having a core coated with a hard outer shell. The core can be of various forms, including for example, gums, candies and jellies. Furthermore, coated comestible may be used for medicinal purposes.

*Buehler et al.* discloses a chewable product with a gelatin matrix that may include a hydrocolloid and water.

Applicants respectfully submit that the proposed combination of *Lee*, *Mehta*, *Silva*, *Mackles*, and *Buehler et al.* is based upon hindsight reconstruction. Applicants note that the teachings of *Mehta*, teach away from the proposed combination.

Applicants' invention teaches a texture masking oral dosage form having (a) a unitary soft core, which is comprised of a plurality of active agent particles having an average size of greater than about 50µm, a hydrocolloid, and water, and (b) a brittle shell encasing the

soft core in an amount of from about 20% to about 50% of the total weight of the texture masking oral dosage form and a thickness of from about 500  $\mu\text{m}$  to about 3000  $\mu\text{m}$ , wherein the weight ratio of active agent particles to shell is from about 1.0:0.5 to about 1.0:15 in the texture masking oral dosage form. The Supreme Court cautioned in KSR, “of the distortion caused by hindsight bias and [must] be cautious of arguments reliant upon ex post reasoning.” KSR, 127 S. Ct. at 1742, citing Graham, 383 U.S., at 36 and Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co., 332 F.2d 406, 412 (6th Cir. 1964). Thus, it is respectfully submitted that the § 103 obvious rejections of the pending claims are based on hindsight reconstruction, which is not permissible. Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

Claims 15, 16 and 17 are directed to compositions that are similar to the composition of Claim 1 in many respects. Claims 15, 16 and 17 all include the features of Claim 1. Accordingly, for at least the same reasons discussed above for Claim 1, Claims 15, 16 and 17 are patentable over the proposed combination of *Bealin-Kelly et al.*, *Puglia et al.* and/or *Mackles*, or the proposed combination of *Lee, Mehta, Silva, Mackles*, and/or *Buehler et al.*.

The remaining claims directly or indirectly depend from Claims 1, 15, 16 or 17. Therefore, each of the remaining claims is also patentable for the reasons stated above.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time the claimed invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC §103(a) be withdrawn.

## **Conclusion**

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP0281USNP/VT.

Respectfully submitted,

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